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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,202	12/27/2001	John M. Flack	MTS 0102 PUS	2844

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BROOKS KUSHMAN P.C.
1000 TOWN CENTER
TWENTY-SECOND FLOOR
SOUTHFIELD, MI 48075

EXAMINER	
RINES, ROBERT D	

ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/036,202	FLACK ET AL.	
	Examiner	Art Unit	
	Robert D. Rines	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Reopened Prosecution

[1] In view of the Appeal Brief filed on 1 May 2007, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, Appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office Action is non-final) or a reply under 37 CFR 1.113 (if this Office Action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were paid, then Appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Notice to Applicant

[2] This communication is in response to the Appeal Brief filed 1 May 2007. Claims 1-19 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[3] Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pestotnik et al. (United States Patent Application Publication #2004/0260666) in view of Tannenbaum (United States Patent Application Publication #2003/0019115).

[A] As per claim 1, Pestotnik et al. teaches a patient healthcare management system having a capability to evaluate patient kidney function (Pestotnik et al.; Abstract, paragraphs [0024] [0085]), the system configured to: receive input defining a patient's medical record including the patient's demographic information, medical condition and diagnosis (Pestotnik et al.; paragraphs [0010] [0024] [0083] [0085]); output at least one medical treatment recommendation wherein the

recommendation is based on the patient's medical record (Pestotnik et al.; Abstract and paragraphs [0084] [0085] [0131]) and calculate and output at least one treatment goal for the patient (Pestotnik et al.; paragraphs [0094] [0150] [0151]).

[i] The Pestotnik et al. system and method gathers patient data and evaluates the patient data to identify known or unknown medical conditions and provide decision-supported data to a physician including guidance as to the potential medical conditions of the patient and to aid the clinician in making informed decisions related to patient medical care (Pestotnik et al.; paragraphs [0011] [0017] [0018]). Among the outputs of the Pestotnik system are at least one medical diagnosis and at least one medical care recommendation that are based upon a large expert knowledge base (Pestotnik et al.; paragraph [0022]). Pestotnik et al. further disclose that the expert knowledge base is constructed from information and data from experts within the relevant fields of medicine including Renal diseases (Pestotnik et al.; paragraph [0085]). While Pestotnik et al. specifically disclose an expert knowledge base constructed to accommodate diagnosis and treatment of renal diseases, Pestotnik et al. fail to specifically disclose well-known clinical indicators such as Glomerular Filtration Rate that are commonly associated with renal diseases or compromised renal function.

[ii] However, as evidenced by Tannenbaum, the use of calculators to determine Glomerular Filtration Rate (GFR) from patient data as entered into well-known equations such as the Cockcroft-Gault equation or variants thereof (as disclosed by Applicant), is well-known in the art (Tannenbaum; Abstract and paragraphs [0025]-[0036] and [0047]).

[iii] It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Pestotnik et al. with those of Tannenbaum. Such a combined system and method would have referenced an expert knowledge base to evaluate entered the patient data to identify known or unknown medical conditions and provide decision-supported data to a physician including guidance as to the potential medical conditions of the patient and to aid the clinician in making informed decisions related to patient medical care (Pestotnik et al.; paragraphs [0011] [0017] [0018] [0085]). Further, such a system-enabled method, when specifically configured to assist a physician in diagnosing and treating renal diseases, would have included in the expert knowledge base, calculators/equations for providing information on well-known clinical indicators such as Glomerular Filtration Rate (GFR) as determined by well-known equations such as the Cockcroft-Gault equation and commonly employed variants thereof (Tannenbaum; Abstract and paragraphs [0025]-[0036] and [0047]). The motivation to combine the teachings would have been to assist nephrologists and other healthcare professionals in correctly prescribing doses of medications in patients with renal impairment (Tannenbaum; paragraph [0013]).

[B] As per claim 2, Pestotnik et al. teaches a system wherein the at least one treatment goal for the patient comprises at least one of: a goal blood pressure, a goal lipid level, a goal cholesterol level and a goal hemoglobin A1C level (Pestotnik et al.; paragraphs [0094] [0127]).

[C] As per claim 3, Pestotnik et al. teaches a system additionally configured to receive input

specifying a treatment for the patient (Pestotnik et al.; Abstract and paragraph [0067] [0076])

[D] As per claim 4, Pestotnik et al. teaches a system additionally configured to output an indication as to whether, based on the patient's medical record, the at least one medical treatment goal has been met (Pestotnik et al.; paragraphs [0094] [0151]).

[E] As per claim 5, Pestotnik et al. teaches a system wherein a plurality of clinical treatment algorithms are applied to the patient's medical record to generate the at least one treatment recommendation and the at least one patient treatment goal (Pestotnik et al.; paragraphs [0084] [0094] [0138] [0150] [0151]).

[F] As per claim 6, Pestotnik et al. teaches a system additionally configured to: receive input specifying a patient's current medication(s); receive input specifying a new prescription for the patient (Pestotnik et al.; paragraph [0153]); and generate an alert if the prescribed medication may antagonize a medication the patient is currently taking (Pestotnik et al.; paragraphs [0077] [0154]).

[G] As per claim 7, Pestotnik et al. teaches a system further configured to: receive input defining a plurality of patient medical records comprising patient demographic information, medical condition, diagnosis and treatment (Pestotnik et al.; paragraphs [0010] [0024] [0083] [0085] [0116]); receive input defining at least one medical record parameter to extract from the plurality of medical records (Pestotnik et al.; paragraph [0112]); and automatically generate a report containing an aggregate of the at least one medical record parameter extracted from the plurality of medical records (Pestotnik et al.; paragraphs [0026] [0094]).

[H] As per claim 8, Pestotnik et al. teaches a system further configured to receive input defining a subset of the plurality of patient medical records from which to extract the at least one medical record parameter (Pestotnik et al.; paragraphs [0112] [0153]).

[I] As per claim 9, Pestotnik et al. teaches a system additionally configured to receive input, for each patient encounter with his or her healthcare provider (Pestotnik et al.; paragraphs [0127] [0145]) defining the patient encounter wherein each defined patient encounter is appended to the patient's medical record (Pestotnik et al.; paragraphs [0127] [0128]).

[i] Regarding claims 2-9, the obviousness and motivation as discussed with regard to claim 1 above are applicable to claims 2-9 and are herein incorporated by reference.

[J] Claims 10-18 differ from system claims 1-9 in that claims 10-18 are directed to a method. As per this element, Pestotnik et al. teaches both a method and a system (Pestotnik et al.; paragraphs [0012]-[0118] and [0027]).

[i] The remainders of claims 10-18 repeat the same limitations of system claims 1-9, and are therefore rejected for the same reasons given for those claims.

[K] As per claim 19, Pestotnik et al. teaches a computer-based system for interactively managing patient healthcare and evaluating patient kidney function, the system comprising: a means for defining a patient's medical record (Pestotnik et al.; paragraphs [0010] [0024] [0083] [0085]); a means for generating at least one patient treatment recommendation based on the patient's medical record (Pestotnik et al.; Abstract and paragraphs [0084] [0085] [0131]) and a means for calculating at least one treatment goal for the patient (Pestotnik et al.; paragraphs [0094] [0150] [0151]).

[i] As discussed above with regard to claim 1, while Pestotnik et al. specifically disclose an expert knowledge base constructed to accommodate diagnosis and treatment of renal diseases, Pestotnik et al. fail to specifically disclose well-known clinical indicators such as Glomerular Filtration Rate (estimated or otherwise) that are commonly associated with renal diseases or compromised renal function.

[ii] However, as evidenced by Tannenbaum, the use of calculators to determine Glomerular Filtration Rate (GFR) (as a function of serum creatine, age, and weight) from patient data as entered into well-known equations such as the Cockcroft-Gault equation or variants thereof (as disclosed by Applicant), is well-known in the art (Tannenbaum; Abstract and paragraphs [0025]-[0036] and [0047]). Accordingly, Tannenbaum discloses a means for calculating the patient's estimated glomerular filtration rate based on the patient's medical record (Tannenbaum; paragraphs [0025]-[0036] [0047]).

[iii] Regarding claim 19, the obviousness and motivation to combine as discussed with regard to claim 1 above are applicable to claim 19 and are herein incorporated by reference.

Response to Arguments/Remarks

Applicant's arguments/remarks filed 1 May 2007 have been fully considered by the Examiner and are considered moot in view of newly added grounds of rejection.

In response, all of the limitations which Applicant disputes as missing in the applied references have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Pestotnik et al. and Tannenbaum, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (mailed 12 September 2006), and incorporated herein.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kotler et al., METHOD FOR ESTIMATING CREATINE CLEARANCE IN OBESE AND MALNOURISHED SUBJECTS USING MEASUREMENTS OF BODY CELL MASS, United States Patent #5,865,763.

Estimation of the Glomerular Filtration Rate in NIDDM Patients From Plasma Creatine Concentration After Cimetidine Administration, Frits A W Kemperman, Joseph Silberbusch, Eduard H Slaats, Arieal M Prins et al., Diabetes Care, vol. 21, no.2, February 1998.

Estimation of glomerular filtration rate in cancer patients, JG Wright, AV Brody, M Highley, J Fenwick, A McGill and AH Calvert, *British Journal of Cancer (2001) vol. 84(4), pp. 452-459.*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert D. Rines whose telephone number is 571-272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RDR

7/19/07

JEFFREY A. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600